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103D CONGRESS
1ST SESSION

S. 821

To amend title XVIII of the Social Security Act to provide for uniform coverage of anticancer drugs under the medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 22 (legislative day, APRIL 19), 1993

Mr. ROCKEFELLER introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to provide for uniform coverage of anticancer drugs under the medicare program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare Cancer Coverage Improvement Act of 1993".

SEC. 2. UNIFORM MEDICARE COVERAGE OF ANTICANCER DRUGS.

(a) IN GENERAL.—Section 1861(t) of the Social Security Act (42 U.S.C. 1395x(t)) is amended—

(1) by inserting "(1)" after "(t)";

(2) by striking "(m)(5) of this section" and inserting "(m)(5) and paragraph (2)"; and

(3) by adding at the end thereof the following new paragraph:

"(2)(A) For purposes of paragraph (1) the term 'drugs' includes any drugs or biologics approved by the Food and Drug Administration used in an anticancer chemotherapeutic regimen for a medically accepted indication as described in subparagraph (B).

"(B) The term 'medically accepted indication' means any use of a drug or biologic included under paragraph (1) if such use—

"(i) is included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations and the United States Pharmacopoeia-Drug Information; or

"(ii) is supported by peer reviewed medical literature appearing in publications which have been specifically approved for purposes of this paragraph by the Secretary.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to items furnished

on or after the first day of the first month that begins after the date of the enactment of this Act.

SEC. 3. COVERAGE OF CERTAIN SELF-ADMINISTERED ANTICANCER DRUGS.

(a) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395(s)(2)) is amended—

(1) by striking "and" at the end of subparagraph (O);

(2) by adding "and" at the end of subparagraph (P); and

(3) by adding at the end the following new subparagraph:

"(Q) an oral drug (which is approved by the Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients) which is the same indication and active ingredient (or ingredients) as that for a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B);".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 1994.

SEC. 4. STUDY OF MEDICARE COVERAGE OF PATIENT CARE COSTS ASSOCIATED WITH CLINICAL TRIALS OF NEW CANCER THERAPIES.

(a) STUDY.—The Secretary of Health and Human Services shall conduct a study of the effects of expressly covering the patient care costs for medicare beneficiaries enrolled in clinical trials of new cancer therapies, where the protocol for the trial has been approved by the National Cancer Institute or meets similar scientific and ethical standards, including approval by an Institutional Review Board. The study shall include—

(1) an estimate of the cost of such coverage, taking into account the extent to which medicare currently pays for such patient care costs in practice;

(2) an assessment of the extent to which such clinical trials represent the best available treatment for the patients involved and of the effects of participation in the trials on the health of such patients;

(3) an assessment of whether progress in developing new anticancer therapies would be assisted by medicare coverage of such patient care costs; and

(4) an evaluation of whether there should be special criteria for the admission of medicare beneficiaries (on account of their age or physical condi-

tion) to clinical trials for which medicare would pay the patient care costs.

(b) REPORT.—The Secretary of Health and Human Services shall submit a report on the study required by subsection (a), including recommendations as to the coverage of patient care costs of medicare beneficiaries enrolled in clinical trials of new cancer therapies, to the Committee on Finance of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives, not later than 2 years after the date of enactment of this Act.

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